SUPPRESSED

FILED

OCT - 2 2013

U. S. DISTRICT COURT
EASTERN DISTRICT OF MO
ST. LOUIS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No.
	)	
KAMALDEEP K. SANDHU, and NAVDEEP S. SANDHU,	)	4:13CR410 CEJ/TIA
	)	
Defendants.	)	

INDICTMENT

The Defendants

At all times relevant to this Indictment:

1. Defendant Kamaldeep K. Sandhu was a resident and citizen of British Columbia, Canada. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

2. Defendant Navdeep S. Sandhu was a resident and citizen of British Columbia, Canada. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

3. Defendants, along with others known and unknown to the Grand Jury, operated a business called "online botox.com." Defendants' business obtained adulterated, misbranded, and unapproved prescription drugs from Turkey, smuggled the illegal drugs into the United States using

false and fraudulent customs declarations, and sold them to physicians throughout the United States, including two physicians practicing in St. Louis County, Missouri. Defendants' business marketed these illegal prescription drugs to U.S. doctors with substantially lower prices than the legal FDA-approved versions of the prescription drugs. For example, some of defendants' marketing materials offered "Botox (Turkish)" for $354.99, when the FDA-approved version of Botox® was sold through licensed wholesalers at higher prices in the United States, often for $525. Ultimately, patients in Missouri and elsehwere received the FDA-unapproved drugs without knowing of the illegal source of the drugs. From 2009 through 2013, defendants shipped and caused to be shipped over one hundred separate illegal prescription drug shipments to physicians located within the Eastern District of Missouri.

The U.S. Food and Drug Administration

4. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumers to use them in a safe manner as well as drug labels that identified whether the drugs were manufactured by companies that registered with FDA as drug establishments. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

Prescription Drugs

5. Under the FDCA, drugs included articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and articles intended to affect the structure or any function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (c). A "biological product," defined as a toxin, therapeutic serum, blood, or blood component or derivative applicable to the prevention, treatment, or cure of a disease or condition of human beings, can also be a "drug." 21 U.S.C. § 321(g)(1); 42 U.S.C. § 262(i).

6. Under the FDCA a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

7. Onabotulinumtoxin A is the established name for the drug and biological product marketed in the United States as Botox® Cosmetic. Botox® Cosmetic is a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(1) because of its toxicity or other potentiality for harmful effect. Botox® Cosmetic is the Type A toxin produced by the bacteria *Clostridium botulinum*. The Type A toxin is a highly potent and potentially dangerous toxin, and could cause the disease botulism when present in human beings in a sufficient amount. Botulism is a muscle-paralyzing condition in which the toxin from *Clostridium botulinum* binds to nerve endings at the point where nerves join muscles, preventing the nerves from signaling the muscles to contract. As such, Botox® Cosmetic could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs. On July 31, 2009, FDA approved several revisions to the labeling for Botox® Cosmetic,

including the addition of a "black box warning" under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of Botox® Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Botox® Cosmetic is typically injected directly into patients, making the sterility and efficacy of this prescription drug important. According to the label for FDA approved Botox® Cosmetic, unopened vials of Botox® Cosmetic should be stored in a refrigerator at temperatures between 2° to 8° Celsius before dispensing to patients.

Prescription Devices

8. The FDCA defined a "device" as, among other things, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which [was] . . .intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or function of the body of man or other animals, and which [did] not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which [was] not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(2)(3).

9. A "prescription device" was a device that, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary for its use, was not safe except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.

10. Starting in 2006, FDA approved Juvederm 24HV, Juvederm 30, and Juvederm 30HV Gel Implants, Juvederm Ultra XC, and Juvederm Ultra Plus XC as devices. These devices are hereafter referred to collectively as "Juvederm®"). Juvederm® was a sterile, biodegradable, clear, colorless, homogenized gel implant. It consisted of crosslinked hyaluronic acid, and was intended for injection

into the mid-to-deep skin for correction of moderate to severe facial wrinkles and folds. Juvederm® was regulated as a device because, when injected, it was intended to reside under the skin and did not achieve its primary intended purpose through chemical action or metabolization. FDA's approvals for Juvederm® limited them to use under the supervision of a licensed practitioner

Misbranding

11. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug or device is misbranded under the FDCA if the labeling is false or misleading in any particular. 21 U.S.C. § 352(a). Each drug's label needs to use the established name of the drug and contain a lot number that is capable of yielding the complete manufacturing history of the drug. 21 U.S.C. § 352(e)(1)(A)(i); 21 C.F.R. §§ 201.50(b), 201.18, and 201.100(b)(6). A drug or device was misbranded if it failed to bear adequate directions for its use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layman can use a drug or device safely and for the purposes for which it was intended. 21 C.F.R. §§ 201.5. A drug or device is also misbranded if its labeling fails to bear adequate warnings where use of the drug may be dangerous to the health of users. 21 U.S.C. § 352 (f)(2).

Adulteration

12. A drug was "adulterated" if the methods used in, or the facilities or controls used for its manufacturing, processing, packing, and holding do not conform with current good manufacturing practices ("cGMP") to assure that the drug is safe and has the identity and strength and meets quality and purity characteristics which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

Misbranded and Adulterated Drugs and Devices In Missouri

13. The Juvederm prescription devices sold by defendants to doctors in Missouri and elsewhere had labeling in foreign languages. Other prescription drugs obtained from "online botox"

had different lot numbers on the exterior packaging of the drug than the lot numbers found on the actual vial of the drug. The illegal prescription drugs and devices distributed by defendants through "online botox" were not held, packed, or shipped to U.S. doctors in Missouri and elsewhere in conformity with current good drug manufacturing practices. The methods of holding and shipping these prescription drugs did not keep the prescription drugs at the cold temperatures required by the drugs' labeling, or protect their sterility and efficacy. FDA obtained prescription drugs from "online botox" and tested them at FDA's Forensic Chemistry Center. FDA determined that the labeling for the Botox® it obtained from "online botox" was counterfeit.

14. In January 2013, defendants voluntarily traveled to the State of Washington from Canada for a meeting regarding their illegal prescription drug distribution business. At the meeting, defendants were informed that special agents from the U.S. Food and Drug Administration, Office of Criminal Investigations, were investigating defendants' business and illegal prescription drug shipments to doctors throughout the United States. In response, defendants instructed another person to lie to the special agents about defendants' business and the activities discussed below in Counts 1-5 of this Indictment, destroy records of illegal drug distributions and U.S. physicians/customers, and hide a computer containing records of illegal drug distributions and customers from the special agents. Defendant Kamaldeep K. Sandhu also took a package of drugs that had been returned from a U.S. doctor/customer from the meeting, and disposed of it shortly after leaving the meeting.

COUNT 1 - CONSPIRACY

The Conspiracy and its Objects

15. Paragraphs 1 through 14 are re-alleged and incorporated by reference as though fully set forth herein.

16. From on or about August 14, 2009 through on or about February 28, 2013, the exact dates being unknown to the Grand Jury, in the Eastern Division of the Eastern District of Missouri and elsewhere, defendants

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU

and others, known and unknown to the Grand Jury, knowingly and willfully conspired and agreed together to commit offenses against the United States, to wit:

(a) fraudulently and knowingly importing and bringing into the United States certain merchandise, that is, packages of the prescription drugs and devices bearing false customs declarations, contrary to law, and;

(b) defrauding the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs found in the United States were safe, effective, labeled properly, and stored and shipped in compliance with federal law.

Manner and Means of the Conspiracy

17. The manner and means by which defendants and their coconspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following which occurred during the entire period of the conspiracy:

18. Defendants and their coconspirators obtained prescription drugs and devices from Turkey and other countries from outside the United States, and shipped them to commercial post office boxes located in the State of Washington, near the Canadian border. Defendants and their co-conspirators utilized exterior packaging that concealed the illegal nature of the prescription drug and device shipments from the United States, such as sending packages with customs declarations falsely

describing the contents as "gifts" or "healthcare items and remedies for personal use" with low declared monetary values. Defendants then directed others to stockpile the drugs and devices from these smuggled shipments, and pack and ship smaller quantities to individual doctors throughout the United States as drug and device orders were placed.

Overt Acts

19. In furtherance of the conspiracy, and to achieve the objects thereof, defendants and their co-conspirators, known and unknown, committed and caused to be committed the following overt acts, in the Eastern Division of the Eastern District of Missouri, in the Western District of Washington, and elsewhere:

a. Each of the allegations set forth in Counts 2 through 5 is incorporated and realleged as though restated herein, as an individual overt act done in furtherance of the conspiracy.

b. On or about January 16, 2013, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, during a meeting, defendant **KAMALDEEP K. SANDHU** advised another person with knowledge of their conspiracy to lie to federal agents who were investigating defendant, telling this person that pretending to not know who defendants were when federal agents asked was the "safest bet."

c. On or about January 16, 2013, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, during a telephone call, defendant **NAVDEEP S. SANDHU** advised another person with knowledge of their conspiracy to remove from his office and hide a computer that contained electronic records of defendants' illegal drug transactions from the special agents that were investigating defendants.

All in violation of Title 18, United States Code, Section 371.

COUNT 2

20. The United States adopts paragraphs 1-14 and as for paragraph 20.

21. On or about January 4, 2013, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, defendants

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU,

aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain merchandise, that is, a package containing the drugs labeled in the United States as "Botox®," contrary to law, in that the package's customs declaration stated that it contained a "non commercial gift" valued at "5" when in fact the package contained approximately 50 vials of drugs labeled as "Botox®," that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 353(b)(4)(A) and 352(a), (f)(1), and (f)(2)), in violation of 21 U.S.C. Section 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 3

22. The United States adopts paragraphs 1-14 and as for paragraph 22.

23. On or about December 25, 2012, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, defendants

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU,

aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain merchandise, that is, a package containing devices labeled as "Juvederm®," contrary to law, in that the package's customs declaration stated it contained "healthcare items/remedies for personal use" valued at "USD 115" when in fact the package contained

misbranded prescription devices within the meaning of 21 U.S.C. § 352(a), (f)(1), and (f)(2) in violation of 21 U.S.C. Sections 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 4

24. The United States adopts paragraphs 1-14 and as for paragraph 24.

25. On or about July 9. 2012, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and elsewhere,

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU

defendants herein, with the intent to defraud and mislead, introduced and delivered for introduction, and caused to be introduced and delivered for introduction, into interstate commerce three 100 I.U. vials of drugs labeled as "Botox," that were adulterated by causing the introduction and delivery of these drugs from Washington to a doctor's office in St. Louis County, Missouri. Specifically, each quantity of the drug was adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) because the methods used in, and the facilities and controls used for, its processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practices to assure that the drugs met the requirements of the law as to safety and had the identity and strength and met the quality and purity characteristics which it purported to and represented to possess. All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B), and 18 U.S.C. § 2.

COUNT 5

26. The United States adopts paragraphs 1-14 and as for paragraph 26.

27. On or about January 24, 2012, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and elsewhere,

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU

defendants herein, with the intent to defraud and mislead, introduced and delivered for introduction, and caused to be introduced and delivered for introduction, into interstate commerce two 100 I.U. vials of drugs labeled as "Botox®," that were misbranded by causing the introduction and delivery of these drugs from Washington to a doctor's office in St. Louis County, Missouri. Specifically, each quantity of the drug was misbranded in the following ways:

(a) within the meaning of 21 U.S.C. § 352(a), in that its labeling was false and misleading in any particular, as the lot number on the exterior carton of the drug was not capable of yielding the complete manufacturing history of the drug,

(b) within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling did not bear adequate directions for use;

(c) within the meaning of 21 U.S.C. § 352(f)(2), in that its labeling did not bear such adequate warnings against use in those pathological conditions and by children, where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner or form, as are necessary for the protection of users.

All in violation of 21 U.S.C. §§ 331(a), and 333(a)(2), and 18 U.S.C. § 2.

COUNT 6

28. The United States adopts paragraphs 1-14 and as for paragraph 28.

29. On or about January 16, 2013, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, defendants,

KAMALDEEP K. SANDHU and NAVDEEP S. SANDHU

did knowingly attempt to and did corruptly persuade and engage in misleading conduct by telling another person who had knowledge of defendants' crimes as described above to lie to federal agents, shred paper documents that contained information about defendants' illegal drug transactions and U.S. customers, and hide a computer containing electronic records of defendants' illegal drug transactions and U.S. customers, with the intent to influence, delay, and prevent the testimony of this person in an official proceeding, namely the investigation and prosecution of defendants conducted by the United States Attorney for the Eastern District of Missouri and the Office of Criminal Investigations for the U.S. Food and Drug Administration, in violation of Title 18, United States Code, Section 1512(b)(1) and 1512(i).

A TRUE BILL.

_____
FOREPERSON

RICHARD G. CALLAHAN
United States Attorney

_____
ANDREW J. LAY, #39937
Assistant United States Attorney